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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,446	03/26/2001	Virginia C. Gordon	SAFTY-001BC	2044

7590 12/18/2001
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EXAMINER

TRAN, MY-CHAU T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,446

Applicant(s)

GORDON ET AL.

Examiner

My-Chau T. Tran

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's cancellation of claims 8-66 is acknowledged and has been entered.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "24" and "22" have both been used to designate a lid. "24" is mentioned in the specification to be a lid (pg. 13, line 13) and an air inflow port (pg. 16, line 14) it is unclear if "24" is a lid or an air inflow port or both. Further, reference characters "500" and "512" of figure 15e have both been used to designate a base. Correction is required.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "31" and "26" of figure 5a, "40b" of figure 6, and "OA" of figure 9. Further, the following reference sign(s) mentioned in the description: "108a", "108b", "108c" and "119" for figure 10a are not included in the drawing of figure 10a. Correction is required.
4. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Specification

5. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). Therefore, Section II, Related Application, should appear before Section I, Field of the Invention, and be the first sentence of the specification.
6. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. That is "United States Patent Applications Serial No. 08/723, 636 filed on October 2, 1996" is now "U.S. Patent 5,958,714" and any reference to this application should reflect the change. Correction is required.
7. The disclosure is objected to because of the following informalities:
 - a. "24" is described to be a lid (pg. 13, line 13) and an air inflow port (pg. 16, line 14), it is unclear if "24" is just a lid or just an air inflow port or both.

- b. The description of figure 11 refers to an apparatus "10c" (pg. 21, line 22), which is figure 12. In figure 11, the apparatus is designated as "10b." It is unclear if the description is for figure 11 or figure 12.
- c. In pg. 22, line 25-27, stated that a source of negative pressure is connected to the base 150, which is from figure 11, as to create negative pressure within the cavity 113 of the base 100, which are from figure 10. It is unclear if the apparatus of figure 11 is the same as figure 10 or are these two apparatuses are somehow connected to each other.
- d. There are numerous spelling errors through out the specification. For example on pg. 24 line 25, what is "ant deter" mean or on pg. 27, line 21, is "teast" mean "test."
- e. In page 23, line 22 and page 6, line 29, the word "etc..." is recited. What this phrase means is not clear and clarification or deletion of the phase is requested.
- f. The specification at multiple places refers to an Appendix, which is not part of the specification. The appended material should be incorporated into the specification and given specific page number (37 CFR 1.52). Referring to the material contained within, the Appendices should not be referred to by page number, as US Patents do not have page number but columns. Reference to specific information could be accomplished by referring to the material contained in newly numbered figures or tables. For example page 6, line 20-26 or page 30, line 3 and 5-8.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-7 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The term "n" in claim 1 renders the claim indefinite, because the term "n" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "n" is acknowledged in the art as an infinite integer.

b. Claim 1, line 9, the phrase "may be" is not a positive recitation, therefore, renders the claim indefinite.

c. Claim 5, the phrase "the test apparatus" lacks antecedent basis.

d. Claim 7, the phrase "some of said membrane components" is vague and indefinite as to how many it refers to as "some." Same deficiency is found in claim 67.

The phrase "membrane modules" of claim 67 lacks antecedent basis.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Root et al. (US Patent 4,948,564).

Root et al. disclose a filter strip and composite assemblies for filtering fluids (Abstract; figures 1-15; and col.7, line 63-65). The apparatus comprise of a housing having a cavity (#170 of fig. 9), filtrate-receiving vessels (# 76 and fig. 4), a membrane component (#34 in fig. 3), sample-receiving wells (# 20 and fig. 3), a lid (#202 in fig. 14), air-inlet openings (#209 in fig. 14), and a differential pressure source (fig. 14), which provides a positive or negative pressure within the cavity of the housing. A transfer plate for directing the fluid sample in association with each well (filtrate-receiving vessels) and is a functional equivalent of sample-receiving wells, which are aligned with the filtrate-receiving vessels. The filter strip apparatus is taught to be used with a vacuum manifold (#212 of fig. 15) for applying a pressure differential across the filter membrane and directing the filtrate into the wells or to include a pressure manifold for applying positive pressure above the membranes to enhance sample flow. In another embodiment of the apparatus, a pressure source, #114, that is within the cavity of the housing (fig. 5 and col. 6, line 32-36) would provide a negative pressure.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 7 and 67 rejected under 35 U.S.C. 103(a) as being unpatentable over Root et al. (US Patent 4,948,564) in view of Clarke et al. (US Patent 4,904,394).

Root et al. reference has been disclosed above which fail to explicitly disclose the membrane components and a membrane comprising of a hard material and an elastomeric material. Sanadi disclose a filter element that comprises a membrane made of a hard material 228, and an elastomeric material 204, (fig. 12) in order to provide a seal and prevent cross-contamination of samples (abstract; col. 8, line 1-3). In another embodiment, Sanadi teaches the

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use of a plurality of filters and/or membranes in order to substantially isolate contaminations (col. 2, line 17-23, and col. 8, line 35-36).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the apparatus of Root et al. with a membrane and membrane components, as taught by Sanadi in order to prevent cross-contamination of samples and to substantially isolate contaminations.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Cole et al. (US Patent 4,407,973) is cited to show a multi-well apparatus for determination of an analyte.
- b. Matkovich et al. (US Patent 4,797,259) is cited to show a filtration apparatus for the determination of an analyte.
- c. Clark et al. (US Patent 4,902,481) is cited to show a multi-well filtration test apparatus that consist of a vacuum.
- d. Aysta (US Patent 5,283,039) is cited to show a multi-well filtration device.
- e. Kimura et al. (US Patent 5,418,171) is cited to show a multi-well filtration device, which includes an air inlet opening.
- f. Pocock (US Patent 5,401,637) is cited to show an apparatus for determination of a plurality of analytes.

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- g. Gordon et al. (US Patent 5,578,459) is cited to show a filtration apparatus for the determination of biological samples.
- h. Watts et al. (US Patent 5,807,523) is cited to show an automatic chemistry analyzer.
- i. Gordon et al. (US Patent 5,958,714) is cited to show a filtration apparatus for the determination of biological samples
- j. Fernwood et al. (US Patent 4,493,815) and Franciskovich et al. (US Patent 5,603,899) are cited to show a filtration apparatus for the determination of an analyte.

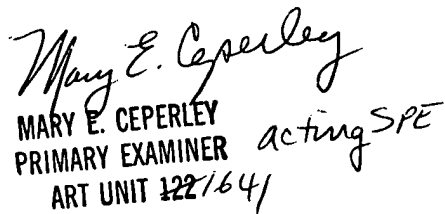
Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



mct
December 4, 2001



MARY E. CEPERLEY
PRIMARY EXAMINER
ART UNIT 122/641
acting SPE